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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,484	02/04/2002	Bob B. Buchanan	416272000200	7171

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MORRISON & FOERSTER LLP
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EXAMINER

NOLAN, PATRICK J

ART UNIT PAPER NUMBER

1644

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/067,484	BUCHANAN ET AL.	
	Examiner	Art Unit	
	Patrick J. Nolan	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 5-13, 19-21, 25-31 and 36-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 14-18, 22-24, 28 and 32-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Claims 1-46 are pending.
2. It is noted that Applicant's confusion over the time period for response is regretted. The Applicant was correct to assume a one month time period for response to a restriction.
3. Applicant's election with traverse of Group I claims, 1-4, 14-18, 22-24, 28 and 32-35 in the reply filed on 11-23-04 is acknowledged. The traversal is on the ground(s) that the Examiner has not demonstrated it would be an undue burden to Examine the groups together. This is not found persuasive because each separate method and product inventions have separate search requirements for application of art that are not substantially coextensive and as such are patentably distinct and would be unduly burdensome to search.

The requirement is still deemed proper and is therefore made FINAL.
4. The claims being examined consonant with the election of Group I are 1-4, 14-18, 22-24, 28 and 32-35.
5. Claims 5-13, 19-21, 25-27, 29-31 and 36-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11-23-04.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. Claims 1-4, 14-18 and 22-24 are rejected under 35 U.S.C. 102(a) or (b) as being anticipated by Del Val et al.(Reference 6 on the IDS submitted 2/3/03).

Del Val et al., teaches the isolated 30 kDa protein from ragweed that is applicant's disclosed protein from which they generated tryptic fragments that resulted in the instantly recited SEQ ID Nos 1-11. Del Val et al., teaches the administration of said protein to dogs, thereby meeting the limitation of a composition comprising a protein. Since the claims are open in the recitation of comprising and each SEQ ID No is a fragment of the 30 kDa protein, the prior art teaches a protein comprising SEQ ID Nos 1-11 or an antigenic fragment comprising SEQ ID Nos 1-11.

It is noted the reference has a publication date of February 2001, and the instantly filed case has an effective filing date of February 4, 2002. Upon a review of the provisional application only 5 of the sequences were disclosed. So the effective filing date of claims 1-4 and 22-24 is 2-4-2002, while the date of claims 14-18 is 2-5-01.

However, it is customary at scientific meetings for abstract books to be available prior to the meeting or at the very least on the first day of the meeting. It is incumbent upon applicant since they have common inventors with the publication to establish when the abstract meeting book was made publicly available so the appropriate statute can be applied.

The prior art teachings anticipate the claimed invention.

7. Claims 14 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,736,149.

The '149 patent teaches an isolated pollen allergen that is a about 30kDa as determined by SDS-PAGE, contains cysteine residues, thereby meeting the limitation of sulfhydryl groups, and possesses allergen activity. The '149 patent also teaches said allergen in pharmaceutical and diagnostic compositions (see Figure 3 and columns 8-11 in particular).

The prior art teachings anticipate the claimed invention.

8. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,500,347.

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The '347 patent teaches diagnostic and pharmaceutical compositions of CK20 or its fragments, of which SEQ ID NO. 21 is 100% identical to applicant claimed SEQ ID NO.9 in positions 16-21 (see columns 1-4 in particular). Since the claims read upon proteins and compositions of proteins comprising SEQ ID NO. 9, the claimed invention is anticipated.

The prior art teachings anticipate the claimed invention.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,500,347 in view of US Patent No. 4,281,061.

The '347 patent has been discussed supra. In addition the '347 patent specifically teaches using antibodies and the protein or peptides thereof in immunological tests.

The claimed invention differs from the prior art teachings only by the recitation of putting said components in a kit with instructions.

However, the '061 patent teaches that reagents for an immunoassay can be provided as kits as a matter of convenience and to optimize the sensitivity of the assay in the range of interest (col 22, line 62 - col 23, line 4).

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Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to be motivated to place the immunoassay components, taught by the '347 patent in a kit as taught by the '061 patent for a matter of convenience. Further it would have been obvious to place instructions in said kit as said instructions are standard in the assay art.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-4, 14, 16-17, 22-24, 28 and 32-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The scope of claims 1 or 22 or 28 or 32 reads upon any protein or polypeptide that comprises SEQ ID Nos 1-11. The scope of claim 14 reads upon any 30kDa polypeptide isolated from any source of pollen extracts. Applicant has described one protein, a 30kDa protein isolated from ragweed that provides written description for base claims 1, 14, 22, 28 and 32. There is no disclosure of what additional amino acid sequences are encompassed by the proteins of claims 1-4 or 32-35 and the fragments of claims 22-24. In addition there is no description of what the additional amino sequences would be in a polymorphic variant comprising SEQ ID NOS 1-11. Lastly, Applicant has not described any other 30 kDa protein besides the protein isolated from ragweed. Therefore, the disclosure of one species does not give adequate written description of a genus of thousands or even possibly millions of proteins or polypeptides encompassed by the claims.

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and

useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claims 2-4 and 22-24 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3 and 8-12 of copending Application No. 10/067,484. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Both sets of claims are drawn to either compositions of proteins or fragments comprising the same exact SEQ ID NOS., as such they are of the same exact scope.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-2, 14-18 and 32-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 8-12 of copending Application No. 10/067,620. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compositions of the copending application comprise the same proteins claimed and a preferred use of said compositions in the copending application is in a kit.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. It is noted references 3 on the IDS submitted 2-3-03 and reference 2 on the IDS submitted 7-12-04 were considered but they were crossed out since they were not appropriate for publishing of the first page of a US Patent.

11. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

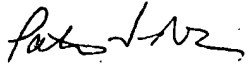
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

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A handwritten signature in black ink, appearing to read 'Patrick J. Nolan'.

Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

February 20, 2005